In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-1973V
Filed: February 16, 2024

GENARINA DECASTRO,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Heather Marie Schneider, The Locks Law Firm, Philadelphia, PA, for petitioner.
Nina Ren, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On December 19, 2017, petitioner, Genarina Decastro, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2018),[2] alleging that the Hepatitis B ("Hep B") vaccine she received on January 2, 2015, caused her to suffer "Bell's palsy and/or off-Table injuries, including but not limited to idiopathic facial paralysis, [Ménière]'s disease, vertigo, inner ear pain, and intraocular pressure." (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is *not* entitled to compensation.

I. Applicable Statutory History

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations,

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). In this case, petitioner has alleged that a Hep B caused her to suffer "Bell's palsy and/or off-Table injuries, including but not limited to, idiopathic facial paralysis, [Ménière]'s disease, vertigo, inner ear pain, and intraocular pressure." (ECF No. 1.) Since petitioner's injuries are not listed on the Vaccine Injury Table relative to the Hep B vaccine, petitioner must establish causation-in-fact.

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

As with a Table Injury, respondent may ultimately prove petitioner's injury to be due to a factor unrelated to vaccination even if petitioner meets his initial burden of proof. § 300aa-13(a)(1)(B). Respondent bears the burden of demonstrating the presence of any alternative cause by preponderant evidence only if petitioner satisfies his *prima facie* burden. § 300aa-13(a)(1)(B); *Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1150 (Fed. Cir. 2007). However, respondent may also present evidence relating to an alternative cause to demonstrate the inadequacy of petitioner's evidence supporting her case in chief. Nonetheless, petitioner does not bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a *prima facie* case under *Althen*. *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352-53 (Fed. Cir. 2008); *Walther*, 485 F.3d at 1150.

II. Procedural History

Petitioner filed records marked as Exhibits P1 through P33 between December of 2017 and October of 2019. (ECF Nos. 1, 12, 14, 16-17, 22, 29.) On May 8, 2020, respondent filed his Rule 4(c) Report. (ECF No. 36.) Respondent argued that petitioner was not entitled to compensation because (1) "[p]etitioner has filed no expert report in support of the petition, nor has petitioner provided any medical or scientific explanation supporting her claim that Hep B can cause Bell's palsy;" (2) "none of [petitioner's] treating physicians causally related [her] Bell's palsy to her receipt of Hep B vaccine;" and (3) even though petitioner's onset "most likely occurred the same day as her second Hep B vaccination[,] . . . [p]etitioner has offered no medical or scientific evidence to support this as a medically appropriate timeframe to infer a causal relationship with either of her Hep B vaccinations." (*Id.* at 27-31.)

The undersigned ordered petitioner to file an expert opinion supporting her claim. (Non-PDF Scheduling Order, filed May 27, 2020.) However, on September 25, 2020, petitioner filed a status report indicating that she "has been unable to retain an expert willing to author an expert report in support of her claims." (ECF No. 40.) The undersigned provided petitioner thirty days to determine how she intended to proceed. (ECF No. 41.) An Order to Show Cause was then issued giving petitioner a further 90 days to secure an expert opinion supporting her claim. (ECF No. 43.) Petitioner then filed an expert report by pharmacist Gourang Patel, Pharm.D.; a letter from her physician; and an affidavit on February 1, 2021. (ECF No. 44.) (These fillings were given duplicative exhibit designations (Exs. P26-P28).) On July 2, 2021, petitioner filed supporting medical literature, additional medical records, and a supplemental expert report. (ECF No. 48.) (Again, several of these filings included duplicative exhibit designations (Exs. P29-P40).) About a month later, petitioner filed additional medical records and an additional statement of completion. (ECF Nos. 50-51; Exs. P41-P51.)

The undersigned held a status conference on October 18, 2021. (ECF No. 55, p. 1.) The undersigned noted that petitioner's expert's report was limited to Bell's palsy despite her petition having alleged additional conditions. Petitioner confirmed she was seeking compensation for Bell's palsy only. Respondent raised outstanding records requests; however, the undersigned concluded that petitioner's narrowing of her claim to Bell's palsy effectively resolved those requests. (*Id*. at 1.) The undersigned directed respondent to file an expert report addressing petitioner's Bell's palsy claim. (*Id.* at 1-2.)

Respondent filed an expert report by neurologist Veronica Cipriani, M.D. (ECF No. 57; Exs. A-B.) The undersigned held a follow up status conference on February 15, 2022. Petitioner was provided an opportunity to seek a report by "an expert qualified to address the clinical neurology issues" raised in respondent's expert report. Additionally, due to prior filing error, petitioner was directed to file a comprehensive exhibit list to clarify the exhibit designations to be used in the case.[3] (ECF No. 58.) On December 16, 2022, petitioner filed a status report explaining that she had been "unable to secure a qualified neurologist to write an expert report." (Ex. 66, p. 2.) The undersigned held a status conference on January 26, 2023. Petitioner requested an opportunity to confer with Dr. Patel regarding a possible rebuttal report by him, but otherwise agreed that the record of the case is fully developed. (ECF No. 67.) The parties agreed to proceed with briefing pursuant to Vaccine Rule 8(d) after petitioner had filed a supplemental report by Dr. Patel, if any. (*Id*.) Petitioner subsequently confirmed that she had contacted her expert, however, he noted he was unable to comment because "this is outside his area of expertise." (ECF No. 68.)

Petitioner filed a motion for a ruling on the record on May 12, 2023. (ECF No. 69.) She alleged that (1) she "has set forth the expert report . . . providing a reliable

[3] Petitioner filed the requested exhibit list on April 18, 2022. (ECF No. 62.) This decision will follow the exhibit designations contained in that exhibit list. As a result, seven documents filed by petitioner on February 1, 2021, and July 2, 2021, will be referenced by their ECF number as they have no unique exhibit designation. (ECF Nos. 44-2, 44-3, and 48-1 through 48-5.)

medical theory linking [p]etitioner's [Hep] B vaccination to her subsequent development of Bell's palsy;" (2) petitioner's treating physicians "would have considered the vaccination as a trigger" for petitioner's Bell's palsy diagnosis; and (3) she "has established a reasonable temporal relationship consistent with the medical and scientific literature and has established a logical sequence of cause and effect to show that the [Hep] B vaccine can and did cause [her] Bell's palsy." (*Id.* at 4-8.)

Respondent filed his response on June 13, 2023. (ECF No. 70.) He argued that (1) "petitioner has presented no reliable scientific evidence that the Hep B vaccine can cause Bell's palsy;" (2) the evidence petitioner provided regarding a logical sequence of cause and effect between her vaccination and her injury is inadequate because petitioner's treating physician did not opine on the connection between the vaccine and the injury until six years after the event at issue; and (3) "petitioner has not preponderantly established an appropriate temporal relationship" between the vaccination and petitioner's injury. (*Id.* at 11-16.) Additionally, respondent questioned the reliability of petitioner's expert, given his lack of expertise in neurology. (*Id.* at 8-11.) Therefore, respondent argued that petitioner failed to preponderantly establish that her Hep B vaccine caused her Bell's palsy and, as such, the burden has not shifted to respondent. (*Id.* at 16-17.)

Petitioner did not file any reply. Accordingly, this matter is now ripe for a decision. I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. *See Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012); *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual History

a. As reflected in the medical records

Petitioner has submitted an abundance of medical records in this case, including records from before she received her vaccines.[4] While I have reviewed all these records, I will focus on summarizing those most relevant to this case.

Before petitioner received her Hep B vaccine, she regularly attended appointments with a primary care physician and a gynecologist. (Ex. P15, pp. 1-8; Ex. P18, pp.1-8, 13, 19-25, 56-62, 73-79, 113-19, 755-61, 787-92, 796-801, 845-51, 862-68; Ex. P46, pp. 913-51, 1086-115; Ex. P48, pp. 13-14, 42-44, 52-55, 85-88, 95-100, 170-75; Ex. P27.) She was diagnosed with GERD, asthma, cysts, osteoarthritis of the knees, and lumbar radiculitis, for which she underwent epidural steroid injections. (Ex. P18, pp. 428-40, 638-54, 708-14, 736-37, 742-43, 749-50, 760-61, 796-801, 822-35; Ex. P44, pp. 37-38, 57-59; Ex. P47, pp. 18-19, 48-49, 81-86.) Additionally, petitioner sought treatment for major depressive disorder, panic disorder, anxiety disorder, and

[4] Many of the records submitted are repetitive. For the sake of clarity, I will not string cite repeat records.

post-traumatic stress disorder and had a history of migraines. (Ex. P18, pp. 1026-66, 2315-35; Ex. P30, pp. 1-8.) She underwent an MRI on February 5, 2009, due to dizziness. (Ex. P21.) This MRI was unremarkable and found no problem in petitioner's internal auditory canals. (*Id.*) Petitioner began seeing otorhinolaryngologist Douglas Bigelow, M.D., on March 19, 2009. (Ex. P22, p. 2.) Her symptoms included sudden, subjective vertigo, episodic vertigo, continuous lightheadedness, and tinnitus in her left ear. (*Id.*) Dr. Bigelow found no abnormalities on basic functional evaluation. (*Id.*)

In December of 2014, petitioner was notified that she needed a Hep B vaccination. (Ex. P2.) Petitioner received her first dose of the Hep B vaccine on January 2, 2015. (Ex. P11.) Between her first dose and her second dose, petitioner underwent an x-ray of her spine that revealed increased facet sclerosis, but no acute osseous abnormality. (Ex. P15, p. 738.) On February 4, 2015, petitioner saw her primary care physician John Robertson, M.D., for flaring fibromyalgia. (Ex. P13, p. 146.)[5] Petitioner did not mention any reaction to her vaccination. (*Id.* at 146-53.)

Her second dose of Hep B vaccine was administered on February 10, 2015. (Ex. P11.) On that same day, petitioner called Dr. Robertson complaining of right[6] ear pain when she was "drinking soda," which started the day before. (Ex. P30, p.11.) She noted that the pain was "near the tonsil area." (*Id.*) Petitioner called Dr. Robertson again on February 13, 2015, complaining of left ear and throat pain. (*Id.* at 14.) She noted that her ear and throat were swollen. (*Id.*) Dr. Robertson prescribed her ear drops and recommended doing a saline rinse. (*Id.* at 18.) On February 15, 2015, petitioner called Dr. Robertson again and reported that she had been doing the drops and saline; however, her symptoms had only gotten worse. (*Id.* at 22.) Dr. Robertson prescribed Medrol pack. (*Id.*)

Petitioner called Dr. Robertson again on February 15, 2015, and notified him that she had woken up with left sided facial droop and tingling in the left side of her face. (Ex. P30, p. 23.) She reported that she could not close her left eye or taste on the left side of her tongue. (*Id.*) Dr. Robertson's office discussed Bell's palsy with petitioner on this phone call and it was noted that petitioner had been experiencing a "left sided ear/viral issue." (*Id.*) Petitioner saw Dr. Robertson on February 16, 2015, for ear pain, paresthesia on the left side of her tongue and face, and a headache. (Ex. P13, p. 137.) Dr. Robertson prescribed prednisone and Valtrex. (*Id.*) During the physical exam, Dr. Robertson noted that petitioner's left ear was "retracted." (*Id.* at 144.) He noted that her left eye was red and that she could not "close the eye with blinking." (*Id.*) Additionally, he noted that she was unable to furrow her brow or close her eye. (*Id.*)

On February 17, 2016, petitioner refused her third dose of the Hep B vaccine due to an "allergic reaction." (P11.) On February 18, 2015, petitioner underwent x-rays that

[5] This exhibit contains multiple sets of page numbers that may be confusing. Therefore, for the sake of clarity, I will use the PDF page numbers in citations of this exhibit.

[6] This record misattributes petitioner's injury to her right side; however, most other records correctly identify petitioner's injury to her left side.

showed underlying degenerative arthritis in both her knees. (P18, p. 622.) That same day, she saw an orthopedist David Gealt, D.O., for bilateral knee degenerative disease. (*Id.* at 1355.) Petitioner was treated with Synvisc One followed by a Depo-Medrol injection. (*Id.*)

Petitioner called Dr. Robertson on February 23, 2015, to report that her face was painful and her left nostril was bleeding. (Ex. P30, p. 35.) She requested a computed tomography ("CT") scan. (*Id.*) She reported no change after taking the Valtrex. (*Id.* at 36.) Dr. Robertson recommended an MRI and made a referral to an otolaryngologist for an evaluation and to an ophthalmologist for her eye. (*Id.*)

Petitioner saw Dr. Robertson on February 24, 2015, with a chief complaint of facial droop and for a follow up for Bell's palsy. (Ex. P18, p. 137.) Petitioner reported that she was attempting to schedule an appointment with an otolaryngologist and had an appointment with an ophthalmologist for later that day. (*Id.*) During the physical exam, Dr. Robertson noted that petitioner was unable to close her left eye completely. (*Id.* at 143.) Additionally, he reported that petitioner was suffering from left facial paralysis and could not furrow her forehead. (*Id.*) Petitioner reported that her jaw was tender on the left side. (*Id.*) Petitioner saw an ophthalmologist at Soll Eye, P.C. later that day. (Ex. P17, p. 21.) Petitioner's chief complaint was noted as Bell's palsy, which began one week prior, and pain in her left eye. (*Id.*) Petitioner also underwent a CT scan which found "[c]hronic stable trace mucosal thickening of the right maxillary sinus. No evidence of acute or chronic sinusitis elsewhere. If there is a clinical desire to evaluate for Bell's palsy, dedicated MRI with contrast would be recommended." (Ex. P18, p. 745.)

On March 2, 2015, petitioner saw Jerrold Aaron Friedman, M.D., for a physical therapy appointment. (Ex. P18, p. 440.) During this appointment, petitioner reported receiving the Hep B vaccine roughly two weeks prior and then developing "left sided headache face and ear pain." (*Id.* at 441.) She explained that she "was diagnosed with Bell's palsy and [had] completed a course of Valtrex and prednisone." (*Id.*) She reported using ointment on her eye and that her pain was an 8 out of 10. (*Id.*) At this appointment, petitioner underwent acupuncture treatment for her pain. (*Id.* at 444.) Dr. Jerrold Friedman noted that her diagnosis was "[f]acial paralysis on left side – suspected [B]ells." (*Id.*) Later that day, petitioner underwent an MRI, that revealed "[n]o acute intracranial pathology. Partially empty sella. Enhancement of the left facial nerve consistent with the diagnosis of Bell's palsy. This likely is related to ongoing inflammatory change." (*Id.* at 605.)

Petitioner saw an otolaryngologist Nathan Deckard, M.D., on March 4, 2015. (Ex. P12, p. 1.) This record incorrectly states that petitioner received her Hep B vaccine on February 11; however, it also notes that, "two days later [petitioner] began to get tongue numbness, eye pain in vesicles over the injection site, as well as over the cranial nerve V distribution bilaterally." (*Id.*) Dr. Deckard reported that petitioner had a history of chickenpox, but "denies any history of shingles." (*Id.*) Petitioner also explained that she had woken up with left-sided facial palsy and ear pain. (*Id.*) Petitioner explained

she had taken prednisone, Valtrex, and Augmentin, but did not experience any improvement. (*Id.*) Petitioner denied hearing loss, otorrhea, or vertigo. (*Id.*) Dr. Deckard diagnosed petitioner with Bell's palsy, encouraged her to continue treating her eye with tape and ointment, recommended that she undergo an electroneurography ("ENoG"), and referred her to a surgeon. (*Id.* at 2.) On the same day, petitioner also saw Dr. Robertson. He reported she was seeing specialists for her Bell's palsy treatment. (Ex. P18, p. 155.)

On March 10, 2015, petitioner attended physical therapy where she reported "decreased left-sided face pain and ear pain." (Ex. P18, p. 445.) At this appointment, petitioner underwent acupuncture to treat her facial paralysis and pain. (*Id.* at 448-49.) The next day, petitioner underwent an ENoG that showed "no measurable or observed response from the left facial nerve when stimulated." (Ex. P8, p. 29.)

Petitioner saw the ophthalmologist again on March 17, 2015, for treatment of her Bell's palsy. (Ex. P18, p. 601.) Petitioner had a physical therapy appointment on March 20, 2015. (*Id.* at 449.) She again reported "decreased left-sided face pain and ear pain." (*Id.* at 450.) She underwent acupuncture at this appointment. (*Id.* at 452-53.) Petitioner's next physical therapy appointment was on March 25, 2015. (*Id.* at 454.) She underwent another round of acupuncture. (*Id.* at 457.)

On April 1, 2015, petitioner had another physical therapy appointment. (Ex. P18, p. 458.) She again reported decreased pain in both her face and ear. (*Id.*) Petitioner underwent another round of acupuncture. (*Id.* at 461-62.) Petitioner was instructed to apply for leave under the Family and Medical Leave Act on April 2, 2015. (Ex. P24, p. 137.) On April 7, 2015, petitioner had an appointment with Dr. Robertson. (Ex. P15, p. 169.) Dr. Robertson noted that petitioner was seeing a physical therapist and an otolaryngologist, as well as undergoing acupuncture to treat her Bell's palsy. (*Id.*) It was further noted that she planned to see a neurologist. (*Id.*)

Petitioner had another physical therapy appointment on April 14, 2015. (Ex. P18, p. 462.) Dr. Jerrold Friedman reported that petitioner had decreased pain; however, she still had difficultly closing her left eye and significant facial asymmetry. (*Id.* at 463.) At this visit, she underwent acupuncture to treat her symptoms. (*Id.* at 466.) Petitioner's next physical therapy appointment was on April 22, 2015. (*Id.* at 467.) Dr. Jerrold Friedman again reported decreased pain, difficultly closing the left eye, and significant facial asymmetry. (*Id.*) Petitioner's acupuncture treatment continued during this appointment. (*Id.* at 470-71.)

Petitioner began seeing a neurologist Andrew McGarry, M.D., for her Bell's palsy on April 24, 2015. (Ex. P42, p. 9.) Petitioner reported that, four days after she received her Hep B vaccine, she had developed an "itchy, bumpy, erythematous rash" on the left side of her face and vesicles on the tongue and lips. (*Id.* at 15.) The next day she developed an earache, numbness in her tongue, and weakness in the left side of her face. (*Id.*) Dr. McGarry noted that petitioner had a history of vertigo, tinnitus, and falling on the left side, which was "occasionally associated [with] eye pain, headaches, and ear

pain on that side." (*Id.*) Dr. McGarry confirmed petitioner's diagnosis of Bell's palsy. (*Id.* at 21.)

On May 13, 2015, petitioner saw an ophthalmologist for a follow up for left Bell's palsy. (Ex. P18, p. 597.) Petitioner saw Dr. Robertson for generalized body aches on May 27, 2015. (*Id.* at 184.) During this appointment, she reported that she was following up with specialists regarding her Bell's palsy. (*Id.*) She stated that her eye is getting less dry and that she planned to continue acupuncture to treat her symptoms. (*Id.*) Dr. Robertson reported "[s]ome movement mild noted on the eye and ey[e]brow, facially as well." (*Id.*) Petitioner had another follow up appointment with her ophthalmologist on July 1, 2015, for left eye exposure keratitis. (*Id.* at 595.)

Petitioner had a primary care appointment with Dr. Robertson on July 6, 2015. (Ex. P13, p. 86.) Dr. Robertson reported that petitioner's Bell's palsy was stable, and that physical therapy was helping with her facial strength. (*Id.*) Petitioner stated that she was seeing an ophthalmologist who recommended seeing a surgeon for possible nerve release. (*Id.*) During her physical examination, Dr. Robertson reported "improvement in smile and eye closing." (*Id.* at 92.)

Petitioner began seeing otolaryngologist Thomas Spalla, M.D., on September 22, 2015, for facial droop. (Ex. P41, p. 15.) She reported that she had been attending physical therapy but had been told to stop. (*Id.* at 16.) Petitioner explained that she had been experiencing contractions in her eye, pain above her left medial brow, and occasional left ear fullness. (*Id.*) Dr. Spalla noted that petitioner's eye did not close completely and that her mouth was asymmetrical. (*Id.*) Dr. Spalla diagnosed petitioner with blepharospasm and recommended treating with Botox. (*Id.* at 20.) Additionally, Dr. Spalla recommended continuing physical therapy to treat petitioner's left-sided facial paralysis. (*Id.*)

On October 6, 2015, petitioner saw her ophthalmologist for a follow up on her exposure keratitis. (Ex. P18, p. 593.) Petitioner had an appointment with Dr. Robertson on October 16, 2015, regarding finger pain, joint pain, and fatigue. (Ex. P13, p. 76.) Dr. Robertson noted that petitioner was seeing an otolaryngologist for her Bell's palsy treatment and treating her symptoms with Botox. (*Id.*) Petitioner underwent imaging of her hands on October 20, 2015, with normal results. (Ex. P18, p. 741.) On October 21, 2015, petitioner had an appointment with a rheumatologist Hala Eid, M.D., for fibromyalgia. (Ex. P18, p. 2181.) Dr. Eid noted that petitioner had been diagnosed with Bell's palsy "one year ago in February after receiving the hepatitis B vaccine." (*Id.*) Petitioner reported that her pain increased when she was diagnosed with Bell's palsy. (*Id.*)

Petitioner had her next ophthalmology appointment on November 9, 2015, to follow up on her Bell's palsy and exposure keratitis. (Ex. P18, p. 608.) Petitioner's left eye was irritated, and it was noted that she was experiencing a left hemifacial spasm. (*Id.* at 608-09.) It was recommended that she undergo Botox to treat the spasm. (*Id.* at 609.) Two days later, on November 11, 2015, petitioner had an appointment with Dr.

Robertson. (*Id.* at 290.) Dr. Robertson reported that petitioner was planning on treating her left-sided facial spasm with Botox. (*Id.*) During the physical exam, Dr. Robertson reported that petitioner's Bell's palsy was improving, and that petitioner's facial spasm was not "seen in this office." (*Id.* at 296.) During this time, petitioner was also being treated for back and leg pain. (*Id.* at 621-22, 738, 988-1000.)

On December 2, 2015, petitioner had an appointment with her ophthalmologist. (Ex. P17, p. 12.) Petitioner underwent Botox to treat her left hemifacial spasm. (*Id.* at 13.) Petitioner had another appointment with her ophthalmologist two weeks later, on December 16, 2015. (*Id.* at 10.) It was noted that petitioner experienced mild exposure keratopathy following her Botox injection and that the dosage should be decreased. (*Id.* at 11.) On December 5, 2015, petitioner received a letter notifying her that her worker's compensation claim was under review. (Ex. P24, p. 63.)

On January 13, 2016, petitioner had an appointment with Dr. Robertson for back pain. (Ex. P18, p. 303.) During this appointment, she updated Dr. Robertson on her Bell's palsy and reported that she had a bad reaction to a Botox injection but was getting a bit better. (*Id.*) She explained that her doctors had discussed a pain management procedure. (*Id.*) On the same day, petitioner saw her ophthalmologist for a follow up. (*Id.* At 586.) During this appointment, it was noted that she had a bad reaction to Botox and is scheduled for a left sided nerve block. (*Id.* at 586-87.) Petitioner had a preoperative appointment on January 14, 2016, for a trigeminal nerve block with fluoroscopy for her left facial droop. (*Id.* at 976-81.) During this time, petitioner was also being treated for right hip pain. (Ex. P47, p. 344; Ex. P18, pp. 973-76.)

Petitioner had another preoperative appointment on January 29, 2016, for another trigeminal nerve block with fluoroscopy to treat her facial pain and droop. (Ex. P18, pp. 968-72.) She underwent the procedure on February 5, 2016. (*Id.* at 966-67.) Petitioner had an eye examination on February 24, 2016. (Ex. P17, p. 29.)

On March 23, 2016, petitioner had a follow up appointment with Dr. Robertson regarding other complaints. (Ex. P18, p. 655.) At this appointment, Dr. Robertson noted that petitioner was taking Flexeril to help with her facial spasms. (*Id.*) During the physical exam, Dr. Robertson reported that petitioner still had a "[m]ild left-sided lower facial droop." (*Id.* at 662.)

Petitioner's next primary care appointment was on April 6, 2016. (Ex. P18, p. 665.) She complained of wheezing and anxiety. (*Id.* at 665-66.) She noted that she was depressed and planned on seeking treatment. (*Id.*) Petitioner had an initial assessment at Meridian Counseling Services on that same day. (*Id.* at 2336.) In this initial visit, petitioner explained that she was "greatly stressed at work and has Bell's palsy and fibromyalgia which leaves her in pain all day long." (*Id.*) Petitioner filed a request for medical leave to attend doctors' appointments related to her Bell's palsy and temporary disability insurance. (Ex. P18, p. 1691-820.)

On April 27, 2016, petitioner had a follow up appointment with her ophthalmologist for her nerve block. (Ex. P18, p. 584.) On the next day, April 28, 2016, petitioner had a follow up appointment with her neurologist, Dr. McGarry. (*Id.* at 625.) During this appointment, Dr. McGarry noted that petitioner's Bell's palsy had improved, but she still experienced some facial spasms. (*Id.*) Petitioner tried to treat these spasms with Botox without much relief. (*Id.*) Dr. McGarry reported that petitioner was diagnosed with Ménière's disease and noticed that her balance had been "somewhat off" recently. (*Id.*) Additionally, petitioner explained that she had been experiencing roughly 3-5 migraines per week. (*Id.*)

Petitioner had a pain management appointment on May 4, 2016, with advanced practice nurse ("APN") Diana Eisenstein. (Ex. P18, p. 960.) She complained of "medial left brow pain and point tenderness caused by left facial cramping." (*Id.*) APN Eisenstein noted that petitioner underwent a nerve block, which gave her more control over her facial spasms and "relieved a significant amount of [her] facial pain" for one to two weeks. (*Id.*) Additionally, she complained of continued back and leg pain. (*Id.*) On the same day, petitioner saw her counselor and reported a great deal of pain. (*Id.* at 2340.) Petitioner had a primary care appointment on May 8, 2016, to discuss her anxiety and pain. (*Id.* at 675.) During this appointment, petitioner discussed how she was seeing specialists for her "facial spasm/right forehead spasm" and Ménière's disease. (*Id.* at 676.) Petitioner thereafter received a Synvisc injection in her knee joint to treat her knee pain on May 17, 2016. (*Id.* at 620.)

On May 20, 2016, petitioner saw Dr. Spalla for an evaluation of her facial droop. (Ex. P41, pp. 31-32.) Petitioner explained that "[s]he felt that she was back to the way she was initially with Bell's palsy," and the spasm in her left eye was interfering with her ability to work. (*Id.* at 32.) Petitioner saw her counselor on May 25, 2016, and reported she was considering going on permanent disability. (Ex. P18, p. 2341.)

Petitioner had a follow up appointment with otolaryngologist Dr. Deckard on June 6, 2016, regarding her Bell's palsy.[7] (Ex. P41, pp. 56-57.) Dr. Deckard gave a detailed summary of petitioner's treatment history, noting that petitioner had first been treated with "a high dose prednisone taper and Valtrex." (*Id.* at 57.) Petitioner also tried acupuncture therapy and had seen multiple specialists. (*Id.*) He noted that petitioner was suffering from blepharospasms, pressure behind her left eye, and severe headaches. (*Id.*) On June 15, 2016, petitioner had a primary care appointment with Dr. Robertson. (Ex. P18, p. 388.) Dr. Robertson reported that petitioner was seeing specialists for treatment of her Bell's palsy. (*Id.*) On the same day, petitioner had appointments with both her otolaryngologist and her counselor. (*Id.* at 603, 2342.) During her counseling appointment, she discussed going on "total disability and what kind of coverage she is eligible to receive from her job because . . . [her injury] occurred

[7] In addition to the below, petitioner also sought treatment throughout June, July, August, September, and October of 2016, for her back pain and cervical radiculitis and underwent lateral sensory branch radiofrequency thermal coagulation and cervical epidural steroid injections. (Ex. P18, pp. 903-53, 1266-78; Ex. P47, pp. 514-15, 622-24, 733-36, 936-38, 981-83, 1026-29, 1137-39, 1258-60.) During this time, petitioner also continued to undergo mental health treatment. (Ex. P18, pp. 2342-46.)

on the job." (*Id.* at 2342.) Petitioner again applied for disability benefits through the Social Security Administration on June 24, 2016. (*Id.* at 473-96.)

Petitioner's leave from work was extended on July 1, 2016. (Ex. P18, pp. 1727-33.) On July 28, 2016, petitioner saw otolaryngologist Dr. Bigelow. (Ex. P5, p. 1.) During this appointment, petitioner explained that

> she received the second [Hep] B vaccine February 2015 and the next day developed left earache, left eye pressure, left facial rash and fever. In the following days, she developed sores in the mouth and about [four] days after the onset of symptoms she developed a left-sided facial weakness. Approximately [five] months later, she started having episodes of dizziness, without vertigo. [She] report[ed] bilateral tinnitus that has gotten wor[se] since the [Bell's] palsy.

(*Id.*) Additionally, petitioner complained of "a daily headache," left eye pain, fullness in her left ear, and imbalance. (*Id.*) Dr. Bigelow's assessment was left facial weakness and associated left ear pain. (*Id.* at 4.) During his assessment, Dr. Bigelow considered that petitioner's symptoms may be evidence of Ramsay Hunt syndrome and noted that petitioner's recovery was significant, but incomplete. (*Id.* at 4-5.) On this day, petitioner also had an audiologic reassessment that revealed "normal hearing sensitivity with excellent monosyllabic word recognition" in both of petitioner's ears. (Ex. P8, p. 28.) Petitioner had a follow up appointment with Dr. Robertson, who reported that petitioner continued to see specialists for her Bell's palsy treatment. (Ex. P18, p. 400.) On the same day, petitioner also had a follow up appointment with her ophthalmologist. (*Id.* at 582-83.)

Petitioner's leave from work was again extended through August 2016. (Ex. P18, pp. 1734-40.) On August 23, 2016, petitioner had a follow up appointment with otolaryngologist Oren Friedman, M.D. (Ex. P8, p. 13.) Dr. Oren Friedman summarized petitioner's course of treatment noting that petitioner developed facial paralysis in February 2015. (*Id*.) He explained that:

> Immediately after receiving her first [Hep] B vaccine shot she developed a rash along the left arm where the injection took place. One month later she got the second shot and she developed [a] worse rash and swelling of the left arm, severe pain of the left ear, pain and ulcers in the mouth on the left side of the mouth and tongue only. One to two days after the second injection she developed paralysis of the left side of her face with severe spasms for which she underwent injections with botulinum toxin. She underwent ENoG which reportedly show[ed] complete denervation. She has undergone physical therapy but there has been no progress in her recovery of facial nerve function.

(*Id.*) Dr. Oren Friedman reported that petitioner's current symptoms at the time of the appointment included left-sided facial weakness, "occasional frontal pain tenderness

and pressure," left eye pain, and incomplete recovery of her left facial nerve. (*Id.*) Dr. Oren Friedman opined that petitioner's symptoms were "associated" with her Hep B vaccination "in timing" but also suggested that it could have "perhaps" been "a reactivation of Herpes Virus [that] led to the symptoms of pain and paralysis." (*Id.* at 16.) He directed petitioner to pursue additional physical therapy and to continue undergoing Botox treatment. (*Id.*)

At the end of August, petitioner requested to extend her leave until November 1, 2016; however, this request was ultimately denied. (Ex. P18, pp. 1741-63.) Petitioner had a physical therapy appointment with physical therapist ("PT") Una Velasquez-Manoff on September 1, 2016. (Ex. P9, p. 1.) During this appointment, petitioner reported that she had an adverse reaction to her Hep B vaccination beginning in February 2015. (*Id.*) PT Velasquez-Manoff noted that petitioner's treaters ruled out stroke and diagnosed her with Bell's palsy. (*Id.*) Petitioner's symptoms at this appointment included left-sided facial paralysis, left-sided jaw pain, fullness in left ear, pressure in left eye, and headaches. (*Id.*) PT Velasquez-Manoff recommended continuing physical therapy one to two times a week for six weeks. (*Id.* at 6.) On September 8, 2016, petitioner had a follow up appointment with her neurologist, Dr. McGarry, for Bell's palsy, migraines, and vertigo. (Ex. P18, p. 1246.) He reported that petitioner's Bell's palsy had improved, albeit incompletely, with Botox treatment. (*Id.*) The next day, on September 9, 2016, petitioner had a follow up appointment with Dr. Robertson, during which she noted that she was concerned with her left eye being puffy, planned to undergo Botox, and wished to go to a different physical therapist. (*Id.* at 1883-84.) Petitioner saw Dr. Oren Friedman on September 14, 2016, for a Botox injection. (Ex. P8, pp. 10-12.) Petitioner had a follow up appointment with Dr. Oren Friedman on September 28, 2016. (*Id.* at 7.) During this appointment, Dr. Oren Friedman reiterated his opinion regarding a potential cause of petitioner's symptoms. (*Id.*) At this appointment, petitioner received another Botox injection. (*Id.* at 8-9.)

On September 2, 2016, petitioner filled out a work activity report for the Social Security Administration in reference to her disability benefits. (Ex. P18, pp. 1105-11.) On September 6, 2016, petitioner underwent a psychological evaluation for disability. (*Id.* at 1099-103.) She described her presenting problem as including "Bell's palsy from the Hep B shot," "depression prior to that but . . . worse now," and "panic attacks weekly that are very bad." (*Id.* at 1099.) Petitioner reported a history of outpatient therapy for pain and anxiety, fibromyalgia, Bell's palsy, asthma, and vestibular dysfunction. (*Id.* at 1100.) The psychologist conducting the exam recommended that petitioner attend outpatient therapy. (*Id.* at 1103.) In September of 2016, the Social Security Administration determined that petitioner's conditions did not qualify her for disability benefits or keep her from working. (*Id.* at 1154-66.)

On October 19, 2016, petitioner had another appointment with Dr. Oren Friedman. (Ex. P8, p. 5.) Dr. Oren Friedman again reiterated his opinion regarding a potential cause of petitioner's Bell's palsy. (*Id.*) During this appointment, Dr. Oren Friedman noted that petitioner was especially concerned with left eye exposure and was experiencing discomfort due to dryness. (*Id.*) Petitioner and Dr. Oren Friedman

discussed surgery, including a lower eyelid canthoplasty and tarsal strip, to improve petitioner's symptoms. (*Id.* at 6.) During an appointment with Dr. Robertson on October 21, 2016, petitioner mentioned she was having surgery for her eye on November 2, 2016. (Ex. P18, pp. 1920-21.)

On November 4, 2016, petitioner underwent a "[r]epair of ectropion with tarsal strip," based on a diagnosis of "[e]ctropion, left lower eyelid associated with facial paralysis." (Ex. P8, pp. 3-4.) After her surgery, petitioner had a follow up appointment with Dr. Oren Friedman on November 16, 2016. (*Id.* at 1.) Dr. Oren Friedman again opined that "perhaps a reactivation of Herpes Virus led to the symptoms of pain and paralysis," while also acknowledging that her left facial paralysis was "associated with [H]ep B vaccination in timing." (*Id.*) Dr. Oren Friedman described how petitioner's lower lid tightness had improved since her surgery; however, she was still experiencing some swelling. (*Id.*) Petitioner noted that she "feels tension like something is pulling" when looking up to her right and that she was still experiencing left eye spasms. (*Id.*) Dr. Oren Friedman planned for petitioner to return after four weeks for a Botox injection. (*Id.* at 2.)

On December 1, 2016, petitioner had a primary care appointment, at which she saw APN Stephanie Tonetta-Sayers. (Ex. P13, p. 15.) During this appointment, petitioner explained that she had undergone surgery for her eye droop and that her spasms had improved since the surgery. (*Id.*) She explained that she developed Bell's palsy and chronic left-sided jaw and ear pain after she received her Hep B vaccination. (*Id.*) Petitioner reported pressure/stabbing pain that was controlled by a trigeminal nerve block and acupuncture. (*Id.*) Petitioner had another appointment with Dr. Robertson on December 9, 2016, for an upper respiratory infection and asthma. (*Id.* at 2.) In December of 2016, petitioner also filed for a reconsideration of the denial of her application for disability benefits through the Social Security Administration. (P18, pp. 1410-36.)

Petitioner had a primary care appointment with APN Tonetta-Sayers on January 10, 2017. (Ex. P4, p. 1.) APN Tonetta-Sayers noted that petitioner was seeing a specialist for her chronic lower back, neck, and facial pain. (*Id.*) During the physical exam, APN Tonetta-Sayers noted that petitioner could not close the left side of her mouth due to her Bell's palsy. (*Id.* at 10-11.) Later that month, on January 26, 2017, petitioner saw Dr. McGarry for a neurology follow up regarding her Bell's palsy and migraines. (Ex. P42, p. 124.) Dr. McGarry reported that, since her procedure in November, petitioner had minimal residual effects, which she had been treating with Botox. (*Id.*)

On February 13, 2017, petitioner had a primary care appointment with APN Tonetta-Sayers. (Ex. P4, p. 26.) Petitioner reported that she was looking for specialists to help manage her Bell's palsy. (*Id.*) During the physical exam, APN Tonetta-Sayers noted that petitioner's left lip/mouth continued to droop, but her Bell's palsy was stable. (*Id.* at 36.) Petitioner's next primary care appointment was on February 21, 2017, during which petitioner reported improvement in migraine frequency with Botox

treatment. (*Id.* at 39.) Her Bell's palsy was again noted as stable on physical exam. (*Id.* at 49.)

Petitioner's next appointment was for a follow up with Dr. Robertson on March 24, 2017. (Ex. P4, p. 112.) Petitioner reported eye pain with her headaches. (*Id.*) On May 1, 2017, petitioner had a follow up primary care appointment with APN Tonetta-Sayers, during which she reported breast pain and a dry cough. (*Id.* at 126.) Petitioner's Bell's palsy is not mentioned in the notes for this appointment. (*Id.* at 126-37.) A week later, on May 8, 2017, petitioner returned for a follow up regarding her asthma, right breast pain, and depression. (*Id.* at 138.) Bell's palsy is again not mentioned in the notes for this appointment. (*Id.* at 138-49.) About two weeks after that, on May 16, 2017, petitioner had another follow up appointment with APN Tonetta-Sayers for asthma and a rash related to cockroaches in her house. (*Id.* at 150.) Again, there is no mention of Bell's palsy in the notes for this appointment. (*Id.* at 150-62.)

On June 30, 2017, petitioner underwent a left trigeminal nerve block to treat her left trigeminal neuralgia, left facial pain, and myofascial pain. (Ex. P47, pp. 1883-84.) On August 15, 2017, petitioner had a follow up appointment with Dr. Robertson regarding depression/anxiety, headache, back pain, and breathing issues. (Ex. P18, pp. 1972-73.) During the physical exam, Dr. Robertson noted petitioner's Bell's palsy. (*Id.* at 1981.) On September 1, 2017, petitioner had another follow up with Dr. Robertson. (*Id.* at 2000.) During the physical exam, Dr. Robertson reported that petitioner had a "[s]light eye and lip lag on the left". (*Id.* at 2008.) Dr. Robertson assessed petitioner with Bell's palsy but noted that her condition was stable and that she planned to see outside specialists. (*Id.* at 2010.) Petitioner's next primary care appointment was on October 6, 2017. (*Id.* at 2024.) It was noted that petitioner was seeing an otolaryngologist for her Bell's palsy. (*Id.*)

On October 11, 2017, petitioner had an appointment with her otolaryngologist, Dr. Spalla, for a follow up reassessment and Botox for her blepharospasms in the left side of her face. (Ex. P41, pp. 76-77.) Dr. Spalla noted that petitioner underwent Botox and a nerve block to control her spasms and pain. (*Id.* at 77.) Dr. Spalla also explained that petitioner was "still experiencing discomfort in the left side of her face," specifically in the "masseteric region." (*Id.*)

On November 28, 2017, petitioner saw rheumatologist Dr. Eid for a follow up appointment with a chief complaint of joint pain. (Ex. P18, p. 2200.) Dr. Eid noted that petitioner "was diagnosed with Bell's palsy after receiving the [Hep] B vaccine," and that her pain had gotten worse since her diagnosis. (*Id.* at 2201.) About a month later, on December 22, 2017, petitioner had a primary care appointment with Dr. Robertson, during which she reported receiving Botox for her headaches. (*Id.* at 2051.) Petitioner's Bell's palsy was noted during the physical exam at this appointment. (*Id.* at 2060.)

Petitioner underwent a diagnostic left trigeminal nerve block to treat her left trigeminal neuralgia and left facial pain on January 3, 2018. (Ex. P47, pp. 2560-61.) Petitioner saw a gastroenterologist on January 22, 2018, where she explained that she

had developed a rash after her first Hep B vaccination, "then after second injection developed reactivation of zoster – rash on left face, arm and then developed [Bell's] palsy." (Ex. P23, pp. 8-9.) She noted some of her treatment history, including steroids, antivirals, and surgery for blepharospasms. (*Id.* at 9.) The next day, on January 23, 2018, petitioner underwent bariatric surgery to remove a hernia. (*Id.* at 45-51.)

On February 2, 2018, petitioner saw otolaryngologist Dr. Spalla for a follow up regarding her ear, jaw, and left eye pain. (Ex. P23, pp. 59-60.) Dr. Spalla recommended suturing the eye to alleviate petitioner's symptoms. (*Id.* at 68.) Petitioner had a rheumatology follow up with Dr. Eid on April 12, 2018. (Ex. P18, pp. 2227-28.) During this appointment, Dr. Eid noted that petitioner suffered from dry eyes and Bell's palsy. (*Id.* at 2228.) Additionally, Dr. Eid again explained that petitioner Bell's palsy diagnosis occurred after receiving the Hep B vaccine and that petitioner's pain had worsened since her diagnosis. (*Id.*) Later that week, on February 7, 2018, petitioner saw a urogynecologist for an unrelated issue. (Ex. P23, pp. 112-19.)

Petitioner began seeing Brian Smith, M.D., for a consultation regarding oral-maxillofacial pain/temporomandibular joint ("TMJ") on April 18, 2018. (Ex. P23, p. 247.) She underwent an x-ray and was instructed to return for a night guard. (*Id.* at 249-50.) Petitioner had a follow up appointment with Dr. Robertson on April 27, 2018, and confirmed she was seeing specialists for her Bell's palsy. (Ex. P18, p. 2086.) Her doctors disagreed on a course of treatment. (*Id.*) Petitioner had a physical therapy appointment on April 30, 2018 for "continued complaints of altered sensation about the left cheek." (*Id.* at 2294-95.) She rated her pain an 8 out of 10. (*Id.*) Petitioner underwent acupuncture at this appointment. (*Id.* at 2300-01.)

On May 9, 2018, petitioner had a pain management appointment with APN Linda McGrane. (Ex. P23, p. 324.) She reported back pain, neck pain, headache, and arm pain. (*Id.*) During this appointment, petitioner noted that she did "not wish to proceed with further injections for the [t]rigeminal pain." (*Id.*) On May 22, 2018, petitioner had a follow up gastroenterology appointment, and on May 23, 2018, petitioner had a follow up with pain management to discuss her right arm pain. (*Id.* at 348-60, 369-77.) Petitioner's Bell's palsy was not mentioned during either of these visits. (*Id.*)

Petitioner underwent a neurological evaluation by Anca Bereanu, M.D., on March 20, 2018, for her workers compensation claim. (Ex. P24, pp. 7-12.) Dr. Bereanu explained that the purpose of the visit was "to render an opinion regarding permanency and impairment." (*Id.* at 7.) During this encounter, Dr. Bereanu reviewed petitioner's history and explained that petitioner experienced a reaction after receiving her second Hep B vaccination, which included a rash, increased temperature, and pain in the left ear. (*Id.* at 7-9.) She noted that an MRI performed on March 2, 2015, showed inflammatory changes in her left facial nerve consistent with Bell's palsy. (*Id.* at 8.) Dr. Bereanu noted that petitioner had been on long term disability since October of 2016. (*Id.* at 9.) Dr. Bereanu diagnosed petitioner with:

1. Status-post [Hep] B vaccination with Recombivax, with significant side effects including severe left Bell's palsy and severe facial pain.
2. Status-post left eye surgery for correction to diminish and aperture of the ocular globe on the left side.
3. Residual disfiguring due to prominent left facial palsy, Bell's type, involving the left orbicularis oculi and left facial musculature weakness with dysfunctional and dysaesthetic implications.
4. Chronic facial pain secondary to spasticity of the left facial musculature as a result of Bell's palsy, requiring ongoing left trigeminal nerve blocks on a monthly basis as well as specific and nonspecific pain medication.
5. Severe reactive depression secondary to the above.

(*Id.* at 11-12.)

Petitioner had a follow up appointment with neurologist Larisa Syrow, M.D., on June 6, 2018. (Ex. P23, p. 386.) Petitioner noted that the Botox was working to decrease her migraines and discussed using Botox for her hemifacial spasm as well. (*Id.*) Petitioner received Botox at this appointment. (*Id.* at 387.) Petitioner had a follow up appointment with Dr. Robertson on June 12, 2018, during which petitioner reported that she was working on treating her Bell's palsy with Botox. (Ex. P18, pp. 2118-19.)

Petitioner underwent a second neurological exam for her workers compensation claim on June 14, 2018. (Ex. P24, pp. 16-26.) This exam was performed by Maria Chiara Carta, M.D. (*Id.* at 16.) Dr. Carta noted that petitioner suffered from "left facial weakness, dysphagia, eye discomfort, and depression," since she received a second Hep B vaccination "at her place of employment." (*Id.* at 17.) Petitioner explained that the day after receiving the vaccination, she woke up with "full-blown complete left-sided facial palsy." (*Id.*) Dr. Carta performed a physical exam and reported that petitioner had "residual left-sided Bell's palsy (CN VII) with blepharospasm in the left eye and facial spams and the left eye has been surgically altered." (*Id.* at 21.) After her exam, Dr. Carta recorded her impression as "[r]esidual of left VII cranial nerve palsy and probable Ramsay Hunt Syndrome." (*Id.* at 24.) She opined "that [a] causal relationship between [petitioner's] Bell's palsy and the vaccination in question is a possible one, as it was outlined by her treating providers. It is plausible that an immune reaction to the vaccine (which she had been administered several times), might have caused a reactivation of latent herpes virus." (*Id.* at 25.)

On August 2, 2018, petitioner had a primary care appointment with Dr. Robertson, during which she reported pain and pressure on the left side of her body. (Ex. P18, p. 2150.) During the physical exam, Dr. Robertson noted that petitioner had left-sided ocular muscle weakness. (*Id.* at 2160.) Dr. Robertson ordered labs and directed petitioner to continue seeing her eye specialists. (*Id.* at 2162-63.) Petitioner saw an eye physician on September 6, 2018, for pain in her left eye, which her doctor attributed to Bell's palsy. (*Id.* at 1532.) Petitioner was diagnosed with iritis. (*Id.*) Petitioner saw a dentist on September 17, 2018, for occlusal device impressions. (Ex. P23, p. 542.) Petitioner had a neurology follow up with physician's assistant ("PA")

Erica Morrison. (*Id.* at 554.) Petitioner reported imbalance, dizziness, and tinnitus that "started to get worse in February or March" of 2018. (*Id.* at 555.) PA Morrison noted that petitioner had a history of Bell's palsy, which began following her Hep B vaccination, and that petitioner continues to suffer from facial paralysis. (*Id.*) Additionally, PA Morrison explained that petitioner also has a history of migraines that are being treated with Botox and pain medication. (*Id.*) On September 24, 2018, petitioner had a follow up with her rheumatologist, Dr. Eid, with a chief complaint of pain. (*Id.* at 586.)

Petitioner saw her neurologist, Dr. Syrow, on October 1, 2018, for Botox for migraines and hemifacial spasm. (Ex. P23, pp. 620-21.) Dr. Syrow noted petitioner's history with migraines and explained that her dizziness/vertigo may be related to her migraines as those symptoms also improved with Botox. (*Id.* at 621.) The following day, petitioner had her pre-operative visit regarding her hernia surgery. (*Id.* at 685-95.) On October 4, 2018, petitioner had a follow up with Dr. Robertson, who briefly described petitioner's continued neurologic and eye issues. (*Id.* at 704.)

On November 21, 2018, petitioner had a physical therapy appointment with Dr. Jerrold Friedman. (Ex. P23, p. 797.) Petitioner reported "continued complaints of altered sensation about the left cheek" and that she "had a medrol pack x3 in the past 6 months with some pain relief." (*Id.* at 798.) Petitioner underwent acupuncture during this appointment. (*Id.* at 803-04.) Petitioner saw Dr. Robertson on November 29, 2018, for a viral infection. (*Id.* at 823-39.)

On January 29, 2019, petitioner underwent a psychiatric evaluation with Chris Winfrey, M.D. (Ex. P25.) During this evaluation, Dr. Winfrey found that petitioner was injured at work and suffered facial disfigurement due to her vaccinations. (*Id.* at 4.) In his opinion, this injury caused petitioner to suffer severe depression, unspecified anxiety disorder, and "[o]ther stress related disorder." (*Id.*)

Petitioner's next appointment was with Dr. Robertson on February 7, 2019. (Ex. P46, p. 814.) During this appointment, she discussed her pain and fibromyalgia generally and noted she had Botox treatment for her headaches. (*Id.* at 815.) On April 1, 2019, petitioner had a follow up appointment with her rheumatologist, Dr. Eid, for her pain. (Ex. P45, p. 206.) On April 12, 2019, petitioner had a primary care appointment, during which she reported that her ophthalmologist had suggested that she may need surgery. (Ex. P46, pp. 851-52.)

On May 14, 2019, petitioner had an appointment with her otolaryngologist, Dr. Oren Friedman. (Ex. P31, p. 6.) During the appointment, Dr. Oren Friedman noted petitioner had a "history of left facial paralysis associated with [H]ep B vaccination in timing, perhaps a reactivation of Herpes Virus led to the symptoms of pain and paralysis." (*Id.*) He explained that petitioner had seen an eye doctor for glasses and "was referred by her ophthalmologist for possible eyelid and eye surgery because she has some dry eye symptoms." (*Id.* at 6-7.) Petitioner received Botox during this appointment. (*Id.* at 8-9.) On July 12, 2019, petitioner underwent surgery on her left

eye. (Ex. P32.) Petitioner had a post-operative appointment on July 16, 2019. (Ex. P31, p. 18.) Although petitioner complained of eye irritation associated with her surgery, she also reported that her eye was feeling "much better." (*Id.* at 18-19.) On July 24, 2019, petitioner had her nightguard for her TMJ adjusted. (Ex. P43, pp. 61-68.) Petitioner went to the emergency room on July 26, 2019, with abdominal pain and vomiting, which was attributed to an unrelated surgery. (Ex. P33.) On October 1, 2020, petitioner saw Dr. Robertson for a primary care appointment. (Ex. P46, p. 988.) During the physical examination, Dr. Robertson noted "[l]eft sided [Bell's] palsy minimal, normal speech and eye closing in casual conversation." (*Id.* at 1001.)

Petitioner continued to seek treatment for her back pain throughout 2017, 2018, 2019, and 2020. (Ex. P47, pp. 1383-84, 1507-08, 1637-39, 1768-70, 2021-22, 2140-42, 2312-14, 2432-33, 2704-05, 2835-36, 2957-59, 3079-80, 3212-15, 3346-47, 3493-94, 3625-26, 3757-61, 3893-95, 4029-31, 4173-74; Ex. P23, pp. 135-44, 448-59, 469-79, 644-55, 759-70.) In 2018, petitioner also visited a podiatrist for ingrown toenails. (Ex. P23, pp. 86-96, 161-66, 737-47.) Additionally, petitioner sought treatment for depression and panic symptoms. (Ex. P18, pp. 2246-85; Ex. P46, pp. 885-902, 961-71.) In the beginning of 2021, petitioner also sought treatment for kidney stones. (Ex. P46, pp. 1026-85.)

b. As reflected in petitioner's affidavits

Petitioner submitted two affidavits in this case. (Ex. P1; ECF No. 44-3.) In her first affidavit, petitioner explains that she received the first of her Hep B vaccinations on January 2, 2015. (Ex. P1, ¶ 4.) She describes how after her first vaccine, she "developed a rash around the vaccination site." (*Id.* ¶ 5.) She received her second Hep B vaccine on February 10, 2015. (*Id.* ¶ 7.) Petitioner describes how, after her second vaccination, she "developed an earache in [her] left ear, eye pressure behind [her] left eye, a facial rash on the left side of [her] face and a high fever." (*Id.* ¶ 8.) A few days later, she notes that she developed sores on the left side of her mouth and tongue. (*Id.*) Four days later, petitioner describes how she developed "left sided facial weakness and facial drooping," and sought care from her primary care physician. (*Id.* ¶ 9.) Her facial nerve eventually "began to recover" and she experienced "a partial recovery of these symptoms;" however, she still lacks complete feeling in her face and experiences daily headaches, left eye pain, and fullness in her ear that causes a mobility imbalance. (*Id.* ¶ 10.) She had surgery on her eye in an attempt to correct her inability to close her left eye lid, but the procedure was not completely successful, and she is "still unable to completely close [her] left eye," resulting in "chronic dryness." (*Id.* ¶ 11.)

In her second affidavit, petitioner explains that she saw her primary care physician and was diagnosed with Bell's palsy on February 16, 2015. (ECF No. 44-3, p. 1.) She explains that, prior to this appointment, she did not mention her Hep B vaccination and, therefore, her primary care physician had no knowledge that her Hep B vaccination could have caused her Bell's palsy. (*Id.*)

IV. Expert Opinions

a. Petitioner's Expert, Pharmacist Gourang P. Patel, B.S. Chem., Pharm. D., M.Sc., B.C.P.S.[8]

Dr. Gourang Patel provided two reports in this case. (ECF No. 44-1, Ex. P40.) However, the supplemental report incorporates the first report in its entirety. (*Id.*) Therefore, the second report is mainly discussed throughout this decision. (Ex. P40.)

In pertinent part, Dr. Patel summarizes petitioner's medical history as follows: "Within one week post the second Hepatitis vaccine administration [petitioner] developed tongue numbness, eye pain, and left-sided facial paralysis. [Petitioner] was subsequently diagnosed with cranial nerve VII (CN-VII) injury also known as Bell's palsy . . . and Hepatitis vaccine was also entered as an allergy to her medical record by 2/16/15." (Ex. P40, pp. 1-2.) Dr. Patel explains that Bell's palsy has been listed "as an adverse event . . . in post marketing reviews" of two commonly administered Hep B vaccines. (*Id.* (citing Engerix-B Package Insert (Ex. P34); Recombivax HB Package Insert (Ex. P35)).)

Dr. Patel describes Bell's palsy as an "acute demyelinating disease of the peripheral nerve system similar to other nervous system disorders," such as Guillain Barré Syndrome ("GBS"). (Ex. P40, p. 2 (citing Yuanyuan Huang et al., *The Clinical Significance of Neutrophil-to-Lymphocyte Ratio and Monocyte-to-Lymphocyte Ratio in Guillain-Barré Syndrome*, 128 INT'L J. NEUROSCIENCE 729 (2018) (Ex. P36)).) Dr. Patel explains that triggers of Bell's palsy include "infections, inflammation, facial trauma, acute cold exposure, and ischemia." (*Id.* (citing Wenjuan Zhang et al., *The Etiology of Bell's Palsy: A Review*, 267 J. NEUROLOGY 1896 (2020) (ECF No. 48-3)).) For example, Bell's palsy can be triggered by a reactivation of a viral infection, such as herpes simplex virus or the varicella-zoster virus. (*Id.* (citing Zhang et al., *supra*, at ECF No. 48-3).) Dr. Patel explains that the reactivated virus is thought to trigger the immune system, which causes damage to the facial nerve. (*Id.* (citing Zhang et al., *supra*, at ECF No. 48-3; Handan Alp et al., *Bell's Palsy as a Possible Complication of Hepatitis B Vaccination in a Child*, 27 J. HEALTH POPULATION & NUTRITION 707 (2009) (ECF No. 48-5)).)

Dr. Patel explains that patients with Bell's palsy have increased concentrations of cytokines, specifically interleukin-6 ("IL-6"), interleukin-1 ("IL-1"), and tumor necrosis

[8] Dr. Gourang P. Patel received his Doctor of Pharmacy from St. Louis College of Pharmacy. (ECF No. 44-3, p. 2.) Additionally, he received his Bachelor of Science in Chemistry from Truman State University and his Master of Science from RUSH Graduate College. (*Id.*) He is a Board Certified Pharmacotherapy Specialist ("B.C.P.S."). (*Id.* at 16.) He is currently employed as an assistant professor at RUSH Medical College in both the Department of Pharmacology and Department of Internal Medicine, an adjunct instructor of Advanced Practice Nursing at Northern Illinois University, and an adjunct assistant professor in the Division of Pharmacy Practice at the Chicago Colleges of Pharmacy. (*Id.* at 2.) Additionally, he is a pharmacist at Willow Lake Pharmacy. (*Id.* at 3.) He has published four textbook chapters, and 37 peer reviewed articles. (*Id.* at 4-7.)

factor-alpha ("TNF-α"). (Ex. P40, p. 2.) These markers are inflammatory markers that "can be elevated with vaccine administration." (*Id.* (citing Seden Demirci et al., *The Clinical Significance of the Neutrophil-to-Lymphocyte Ratio in Multiple Sclerosis*, 126 INT'L J. NEUROSCIENCE 700 (2015) (Ex. P37)).) Dr. Patel cites a study that reviewed adverse neurological events following Hep B vaccination and notes that Bell's palsy was one such adverse event. (*Id.* at 2-3 (citing Frederic E. Shaw, Jr. et al., *Postmarketing Surveillance for Neurologic Adverse Events Reported After Hepatitis B Vaccination*, 127 AM. J. EPIDEMIOLOGY 337 (1988) (ECF No. 48-4)).) This study reported that Bell's palsy occurred within four weeks of vaccination. (*Id.* at 3 (citing Shaw et al., *supra*, at ECF No. 48-4)).) However, Dr. Patel also notes that Bell's palsy can have "an acute and rapid onset (< 72 hours)." (*Id.* at 2.)

b. Petitioner's Treating Physician, John F. Robertson, M.D.

While not an expert in this case, petitioner's primary care physician, Dr. Robertson, submitted a brief letter in support of petitioner's case. (ECF No. 44-2.) He acknowledges that petitioner received the subject vaccination "outside of [his] office" and notes that, "[a]t that time [he] was working on the principle that [petitioner's] Bell[']s [p]alsy was most likely secondary to a viral infection of unknown origin which had started by affecting her left ear." (*Id.*) He explains that

> [i]t is not possible to determine with 100% accuracy the exact virus or conditions that caused her Bell[']s [p]alsy, but had [he] known that there was a [Hep] B vaccination given within such a close proximity to the presentation of symptoms and office encounter, the possibility of a shot reaction would have been part of [his] differential diagnosis at that time.

(*Id.*)

c. Respondent's Expert, Neurologist Veronica P. Cipriani, M.D., M.S.[9]

Respondent's expert submitted one report in this case. (Ex. A.) Dr. Cipriani opines that "there is insufficient evidence to conclude that [petitioner's] facial nerve palsy was more likely than not caused by the [Hep] B vaccine." (*Id.* at 9.)

Dr. Cipriani acknowledges that there is evidence that Bell's palsy can be caused by "[r]eactivation of herpes simplex virus type 1." (Ex. A, p. 4 (citing Donald H. Gilden, *Bell's Palsy*, 351 N. ENG. J. MED. 1323 (2004) (Ex. A, Tab 1)).) However, Dr. Cipriani submits that petitioner suffered from Ramsay Hunt Syndrome, "a peripheral facial palsy caused by reactivation of the varicella-zoster virus," not Bell's palsy. (*Id.*) Symptoms of

[9] Dr. Veronica P. Cipriani received a Doctorate of Medicine from the University of Miami Miller School of Medicine and a Master of Science in Health Studies for Clinical Professionals from the University of Chicago. (Ex. B, p. 1.) She is board certified in neurology and psychiatry. (*Id.*) She currently works as an assistant professor of Neurology in the Biological Sciences Division at the University of Chicago. (*Id.*) She is currently a peer reviewer for *Neurology, Neurology: Neuroimmunology & Neuroinflammation*; *Journal of the Neurological Sciences*; and *JAMA Neurology*. (*Id.* at 3.) Additionally, she has submitted three peer review articles for publication. (*Id.* at 6.)

Ramsay Hunt syndrome include "peripheral facial nerve palsy accompanied by an erythematous vesicular rash in the ipsilateral ear, the hard palate, or on the anterior two thirds of the tongue." (*Id.* at 4-5 (citing C.J. Sweeney & D.H. Gilden, *Ramsay Hunt Syndrome*, 71 J. NEUROLOGY NEUROSURGERY & PSYCHIATRY 149 (2001) (Ex. A, Tab 4)).) Dr. Cipriani notes that petitioner has a history of chickenpox and is therefore likely a carrier of the varicella-zoster virus. (*Id.* at 5.) Dr. Cipriani opines that "the severity of [petitioner's] pain associated with the facial nerve palsy supports an alternative diagnosis to an idiopathic Bell's palsy, as well as the report of a pimple-like rash on her tongue, face, and redness in the throat at the time of the diagnosis." (*Id.* at 8.)

Dr. Cipriani notes that petitioner's expert opined that the Hep B vaccine can reactivate latent herpes simplex virus or varicella-zoster virus. (Ex. A, p. 8.) Dr. Cipriani acknowledges that reactivated herpes simplex virus or varicella-zoster virus can be found in patients with facial paralysis, but the studies cited by petitioner's expert "do not discuss why the viruses are reactivated . . . or the mechanism behind reactivation." (*Id.* (citing Yasushi Furuta et al., *High Prevalence of Varicella-Zoster Virus Reactivation in Herpes Simplex Virus–Seronegative Patients with Acute Peripheral Facial Palsy*, 30 CLINICAL INFECTIOUS DISEASES 529 (2000) (ECF No. 48-2)).) Dr. Cipriani opines that "[f]acial palsy triggered by reactivation of [varicella-zoster virus] is considered a separate entity from Bell's palsy, namely Ramsay Hunt syndrome," and "[t]here is no clear mechanism of why a vaccine would cause a patient to be at higher risk of" a varicella-zoster virus reactivation. (*Id.* at 8-9.) Rather, Dr. Cipriani explains that viral reactivation in Ramsay Hunt syndrome is likely due to immunosuppression. (*Id*.) Additionally, Dr. Cipriani explains that "there is no reliable scientific support for the proposition that the [Hep B] vaccine triggers reactivation of [herpes simplex virus], and the petitioner's expert did not cite any evidence to support his claim that the [Hep] B vaccine caused reactivation of [herpes simplex virus], which then caused the facial nerve palsy." (*Id.* at 9.) Dr. Cipriani further notes that "[t]here are no sizable epidemiological studies that link Bell's palsy and the [Hep] B vaccine." (*Id.* at 8.)

Regardless of whether petitioner suffered from Ramsay Hunt syndrome or Bell's palsy, Dr Cipriani opines that petitioner's condition was not caused by her vaccination. (Ex. A, p. 5.) Dr. Cipriani acknowledges that there are ten "reported cases of Bell's palsy in a report of neurologic adverse reactions after the Heptavax hepatitis B vaccination from 1988;" however, she explains there are no such case reports following the vaccine petitioner received (Recombivax HB vaccine). (*Id.* at 7 (citing Shaw et al., *supra*, at ECF No. 48-4)).) On top of the Heptavax and Recombivax HB vaccines being incomparable, Dr. Cipriani explains that the cited case study believed the at risk onset interval to be 3 weeks, "which is a significantly shorter time course than [petitioner] had after her first dose of Recombivax (over 5 weeks)." (*Id.*) She further notes that "[o]f the 10 reported cases of Bell's palsy in the study, all except one occurred within four weeks of a vaccine dose." (*Id.*) Regarding the second dose of Hep B vaccine, Dr. Cipriani opines that onset of petitioner's Ramsay Hunt syndrome occurred the day *before* that vaccination based on the prodromal ear and neck pain reported by petitioner. (*Id.* at 2-3 (citing Ex. P30, p. 11), 5.) Thus, Dr. Cipriani opines that "onset it not medically

reasonable for an association" between petitioner's symptoms and her vaccination. (*Id.* at 7.)

Dr. Cipriani disagrees with Dr. Patel's opinion that Bell's palsy can be compared to GBS. (Ex. A, p. 8.) Dr. Cipriani explains that "[t]he problem with grouping Bell's palsy in with other peripheral nervous system demyelinating disorders is that Bell's palsy is thought to be caused by a reactivation by herpes simplex virus type I." (*Id.* (citing Gilden, *supra*, at Ex. A, Tab 1).) However, demyelinating diseases like GBS are "thought to be due to an overactive or dysfunctional immune response to self-antigens." (*Id.* (citing Nicola Principi & Susanna Esposito, *Do Vaccines Have a Role as a Cause of Autoimmune Neurological Syndromes?*, 8 FRONTIERS PUBLIC HEALTH 361 (2020) (Ex. A, Tab 2)).) Dr. Cipriani notes Dr. Patel's opinion that "patients with Bell's palsy have increased concentrations of inflammatory cytokines, which can also be elevated in vaccine administration." (*Id.* (citing Ex. P40, p. 2).) Although she acknowledges that vaccines can cause an increase in inflammatory cytokines, Dr. Cipriani explains that "[i]ncreased concentrations of inflammatory cytokines can be seen in a variety of infections, vaccine response[s], autoimmune diseases, and more." (*Id.*) Therefore, Dr. Cipriani opines that there is not necessarily a "causative relationship" between the vaccine and increased cytokines. (*Id.*)

V. Discussion[10]

Under the three-part *Althen* test, a petitioner must demonstrate both that the vaccine(s) at issue "can" and "did" cause the alleged injury. *E.g.*, *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (approving the special master's querying under *Althen* regarding, first, whether the vaccine "can cause" the alleged injury and, second, whether it "actually caused" the injury in the particular case). Whether a vaccine can cause the injury is addressed by petitioner's medical theory presented under *Althen* prong one. Even if the vaccines can cause the injury as a general matter, petitioner must also demonstrate that the vaccines did cause the injury in this specific case. This is addressed under *Althen* prongs two and three, with

[10] In her petition, petitioner alleged both idiopathic facial paralysis (*i.e.*, Bell's palsy) and Ménière's disease as injuries caused by her vaccinations. (ECF No. 1.) The same assertion is included in her motion for a ruling on the record. (ECF No. 69, p. 4.) However, neither filing explains how the two conditions may be related or how Ménière's disease could otherwise be vaccine caused. Notably, petitioner's medical records reflect a diagnosis of Ménière's disease predating either of her Hep B vaccinations. (*See, e.g.*, Ex. P18, p. 2 (Meniere's disease included on "Patient Active Problem List" for an October 17, 2013 encounter with Dr. Robertson).) To the extent petitioner would nonetheless contend that Ménière's disease was aggravated by, or constitutes a further consequence of, her Bell's palsy, resolution of her allegation that the Bell's palsy was vaccine-caused remains dispositive. To the extent petitioner is asserting that Ménière's disease constitutes a separate vaccine-caused injury, such a claim is wholly unsupported on this record and petitioner has waived any argument related to Ménière's disease. (*See* Vaccine Rule 8(f)(1) ("Any fact or argument not raised specifically in the record before the special master will be considered waived . . . .") During a status conference held on October 18, 2021, I cautioned petitioner that upon my review of her expert's report, he had addressed only Bell's palsy, despite petitioner having alleged several conditions. Petitioner confirmed she was pursuing a claim for Bell's palsy only. (ECF No. 55.) Subsequently, petitioner confirmed during a later status conference that the record of the case is fully developed without having filed any additional evidence. (ECF No. 67.)

prong three examining the timing of onset relative to vaccination and prong two examining whether a logical sequence of cause and effect implicates the vaccine as causal.

As explained above, the parties' experts discuss petitioner's condition in reference to two different clinical syndromes of facial paralysis. Petitioner's expert refers to petitioner's condition as Bell's palsy while respondent's expert refers to petitioner's condition as Ramsay Hunt syndrome. (Ex. P40, p. 2; Ex. A, p. 8.) While Bell's palsy is generally considered idiopathic, reactivation of latent Herpes Simplex I virus (the virus that causes cold sores) is among the potential causes. (Ex. A, p. 4; Ex P40, p. 2 (citing Zhang et al., *supra*, at ECF No. 48-3).) Petitioner's expert favors this explanation. (Ex. P40, p. 2.) Ramsay Hunt syndrome, however, refers specifically to facial paralysis caused by reactivation of the varicella-zoster virus, which is the virus responsible for chickenpox and shingles. (Ex. A, pp. 4-5.) Under either approach, the key questions raised under *Althen* prong one are (1) whether the Hep B vaccine can reactivate a latent virus and, (2) if not, whether the Hep B vaccine can otherwise be shown to cause idiopathic Bell's palsy.

Regarding specific causation, two key questions are at issue: (1) whether the timing of onset is compatible with petitioner's vaccination having been the cause of her condition, most notably whether it led to viral reactivation, and (2) whether respondent's expert is persuasive in opining that petitioner's own facial paralysis is best categorized as Ramsay Hunt syndrome – that diagnosis tending to point to a latent varicella-zoster virus, rather than vaccination, as the cause of petitioner's condition. The former question is addressed first as a question of timing pursuant to *Althen* prong three. However, resolution of that analysis is equally relevant to assessing whether there is any logical sequence of cause-and-effect implicating petitioner's vaccination under *Althen* prong two.

Because petitioner has not satisfied her burden of proof under any aspect of the *Althen* test, it is not necessary to separately address whether respondent has established a factor unrelated to vaccination, namely the varicella-zoster virus, as the sole cause of her condition.

a. *Althen* prong one

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (quoting *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004)). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human*

Servs., 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen*, 35 F.3d at 548-49).

Regardless of whether petitioner's condition is better categorized as varicella-zoster-related Ramsay Hunt syndrome or Herpes Simplex I-related Bell's palsy, the key element of Dr. Patel's theory – that the Hep B vaccination can cause the reactivation of a latent virus – is still largely unsupported and entirely unavailing. Dr. Patel merely asserted without explanation that reactivation of latent viruses by the Hep B vaccine is a known phenomenon, attributing such reactivation to "immune modulation" and citing Zhang et al. and Alp et al. (Ex. 40, pp. 2-3.) Zhang et al. is a review of possible etiologies for Bell's palsy. (ECF No. 48-3.) Though it includes a discussion of viral reactivation as a possible cause of Bell's palsy, it does not implicate or in any way reference vaccination as a trigger for reactivation. (*Id*.) Alp et al. is a single case report. (ECF No. 48-5.) Case reports in general constitute only weak evidence.[11] Moreover, this case report is itself couched in hesitant terms. Regarding viral reactivation, the authors state without reference to vaccination only that "[t]here is a concern" that viral reactivation "may be" among the causes of Bell's palsy.[12] (*Id.* at 2.) Casting further doubt on Dr. Patel's assertion, Dr. Cipriani additionally explains, at least with respect to varicella-zoster-related Ramsay Hunt syndrome, that viral reactivation occurs as a result of immune *suppression*. (Ex. A, pp. 4, 8.) Thus, the expected mechanism of viral reactivation likely is not consistent with Dr. Patel's assertion that it can be triggered by an active immune response to vaccination. (*Id*. at 8-9.)

Of course, petitioners are not necessarily obligated to come forward with a mechanism of causation to meet their burden of proof under *Althen* prong one. *Knudsen*, 35 F.3d at 549. However, even setting aside the question of viral reactivation, Dr. Patel's broader assertion of vaccine-causation of Bell's palsy is also largely unsupported. Apart from the proposed mechanism of viral reactivation, Dr. Patel cites

[11] Petitioners in this program often highlight the usefulness of case reports in cases of rare diseases or unusual occurrences. *See, e.g.*, *Patton v. Sec'y of Health & Human Servs.*, 157 Fed. Cl. 159, 166-67 (2021). However, case reports "do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value," even though they are not entirely devoid of evidentiary value. *Paluck ex rel. Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 475 (2012) (quoting *Campbell v. Sec'y of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011)), *aff'd*, 786 F.3d 1373 (Fed. Cir. 2015)); *see also Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-0039V, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014) ("[S]ingle case reports of Disease X occurring after Factor Y . . . do not offer strong evidence that the *temporal* relationship is a *causal* one–the temporal relationship could be pure random chance."), *aff'd*, 125 Fed. Cl. 251 (2014).

[12] Regarding vaccine-causation, the authors instead postulate more broadly that "it is at least theoretically possible" that the Hep B vaccine caused Bell's palsy in a manner similar to how vaccines may cause GBS and other demyelinating disorders. (ECF No. 48-5, p. 2.) However, medical theories that are merely "possible" or "plausible" do not satisfy petitioner's burden of proof. *Boatmon*, 941 F.3d at 1360 (explaining that "a 'plausible' or 'possible' causal theory does not satisfy the standard"). That aspect of Dr. Patel's theory is discussed further below. I have considered this case report in that context as well, but I do not find that it adds substantially to that aspect of Dr. Patel's theory.

the following points: Known triggers of Bell's palsy include infection and inflammation; Bell's palsy may be a demyelinating condition similar to GBS; certain inflammatory cytokines (IL-1, IL-6, and TNF-α) that are known to be elevated post-vaccination have also been observed in Bell's palsy patients; and post-marketing reports have observed neurologic events, including Bell's palsy, following Hep B vaccination. (Ex. P40, pp. 2-3.)

Dr. Patel's reliance on post-marketing experience is not persuasive. As has been explained in prior decisions, post-marketing experience, as included in vaccine package inserts, is not strong evidence. *E.g.*, *Cottingham v. Sec'y of Health & Human Servs.*, No. 15-1291V, 2021 WL 6881248, at *33 (Fed. Cl. Spec. Mstr. Sept. 27, 2021) (collecting cases with regard to the evidentiary value of post marketing experience and concluding it "does not necessarily reflect a scientific basis"), *motion for review denied*, 159 Fed. Cl. 328 (2022), *aff'd per curiam*, No. 2022-1737, 2023 WL 7545047 (Fed. Cir. Nov. 14, 2023). Unlike actual clinical trials, this information comes from passive surveillance without comparison to controls and without attribution of causation. *Accord Bowling v. Sec'y of Health & Human Servs*., No. 18-109V, 2023 WL 6846491, at *9 (Fed. Cl. Spec. Mstr. Sept. 20, 2023) (quoting language from a Fluzone package insert confirming post marketing experience derives from spontaneous voluntary reports). Nor does the fact that vaccines produce some cytokines suffice to constitute a theory of causation without more. *E.g.*, *Kaltenmark v. Sec'y of Health & Human Servs*., No. 17-1362V, 2023 WL 8870299, at *28 (Fed. Cl. Spec. Mstr. Nov. 27, 2023) (collecting cases for the proposition that "[e]ven where there is some reason to suspect a condition may be cytokine mediated, this does not automatically lead to the conclusion that vaccines can cause the injury merely because vaccines produce some cytokine elevations"). Respondent's expert opines that it is not reasonable to compare the causes of GBS to Bell's palsy given that the leading theory for the cause of Bell's palsy is viral reactivation. (Ex. A, p. 8.) And, even assuming *arguendo* that analogy to GBS could be informative, a relationship between the Hep B vaccine and GBS is not preponderantly supported on this record. Moreover, even if some of these points could provide some circumstantial evidence, Dr. Patel does precious little to marry them into a cohesive theory of causation. Even taking these points holistically, Dr. Patel's discussion is at best a superficial treatment that fails to preponderantly support an opinion regarding general causation, especially in light of Dr. Cipriani's contrary opinion.[13]

Accordingly, for the reasons stated above, petitioner has failed to meet her burden with regard to *Althen* prong one.

[13] Notably, some other petitioners have been successful in alleging that vaccines can cause Bell's palsy. However, these determinations were based on more thoroughly developed records and theories, in some cases including more sophisticated discussion of some of the concepts superficially raised by Dr. Patel. *E.g.*, *Sturdevant v. Sec'y of Health & Human Servs.*, No. 17-172V, 2022 WL 3369716 (Fed. Cl. Spec. Mstr. July 19, 2022); *Beraki v. Sec'y of Health & Human Servs.*, No. 17-243V, 2021 WL 4891119 (Fed. Cl. Spec. Mstr. Sept. 20, 2021); *E.A. v .Sec'y of Health & Human Servs*., No. 18-1587V, 2023 WL 2640710 (Fed. Cl. Spec. Mstr. Jan. 24, 2023); *Arredondo v. Sec'y of Health & Human Servs.*, No. 18-1782V, 2023 WL 8181138 (Fed. Cl. Spec. Mstr. Oct. 31, 2023).

b. *Althen* prong three

The third *Althen* prong requires establishment of a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1278. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *reconsideration denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd per curiam*, 503 Fed. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26-29 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

According to Dr. Patel, onset of Bell's palsy unfolds rapidly – within 72 hours. (Ex. P40, p. 2.) However, with regard to timing relative to vaccination, he cites post-marketing experience, which identified episodes of Bell's palsy occurring within 4 weeks of vaccination. (*Id.* (citing Shaw et al., *supra*, at ECF No. 48-4).) While not agreeing with the premise that the Hep B vaccine can cause Bell's palsy, Dr. Cipriani notes that Shaw et al. studied an unrelated formulation of the Hep B vaccine and believed that the at-risk interval for post-vaccination Bell's palsy was three weeks. (Ex. A, p. 7.) Petitioner has not otherwise substantiated any other timing of onset relative to her presentation under *Althen* prong one. For example, petitioner has not specifically discussed the timeframe over which post-vaccination inflammation could purportedly lead to viral reactivation. Thus, by petitioner's metric (which is itself based on minimal evidence), if petitioner's condition is to be attributed to her vaccination, onset must have occurred within three to four weeks of one of her two Hep B vaccinations.

Petitioner received her first dose of Hep B vaccine on January 2, 2015. (Ex P11, p. 1.) Therefore, in order for her condition to be causally connected to that vaccination based on Dr. Patel's opinion, onset would have to have occurred no later than about January 30, 2015. However, she did not receive her second Hep B vaccine until February 10, 2015. (*Id*.) In order for her condition to be causally connected to that vaccination per Dr. Patel, onset must have occurred after February 10, 2015, but by no later than about March 10, 2015. If onset of petitioner's condition occurred during the ten-or-so day period preceding her second vaccination, she has not articulated any basis for inferring vaccine causation. Additionally, if one were to conclude that onset of petitioner's condition occurred on the date of vaccination, petitioner has not substantiated the minimal plausible latency for the theory she proposed.

In her motion for a ruling on the record, petitioner urges that:

> Contrary to what Respondent [has] asserted with regard to Petitioner's symptom onset date, within approximately one day following the administration of the aforesaid Vaccine, namely January 3, 2015, Petitioner

> began to develop a rash around the injection site. While it is true that Petitioner did not seek treatment at this time because she did not feel the severity of the rash was enough to require medical attention, she still developed symptoms within a medically appropriate timeframe to be linked to the Hepatitis B vaccine that she received.

(ECF No. 69, p. 6.) However, this argument is not helpful in resolving this case. Even assuming *arguendo* that petitioner's affidavit should be credited with regard to the onset of the injection-site rash, petitioner has not established either that the injection site rash (as opposed to the later facial rash) is a symptom of her Bell's palsy or in any way a signifier of an underlying disease process leading to Bell's palsy. Her own expert specifically opines that the second Hep B vaccine administered in February, rather than the first vaccine administered in early January, caused her condition. (Ex. P40, p. 3.) Nor does he cite an injection site rash as a factor supporting his opinion. Dr. Patel identifies onset of tongue numbness, eye pain, and left-sided facial paralysis occurring subsequent to the second vaccination as leading to her diagnosis of Bell's palsy and specifies that Bell's palsy develops over the course of no more than three days. (*Id*. at 1-2.) Even accounting for the Dr. Patel's limits of clinical qualifications, it is not clear why petitioner has abandoned Dr. Patel's assessment of onset, and petitioner has not pointed to any medical opinion at all that would support her January 3, 2015 presentation as constituting the onset of the injury she has actually alleged.

In any event, respondent's expert is persuasive in opining that onset of petitioner's condition actually began on February 9, 2015, the day before her second Hep B vaccination. (Ex. A, p. 4.) As Dr. Cipriani explains, Bell's palsy often presents with prodromal neuropathic pain prior to onset of facial weakness. (Ex. A, pp. 4-5 (citing Stephen G. Reich, *Bell's Palsy*, 23 CONTINUUM (MINNEAPOLIS MINN.) 447 (2017) (Ex. A, Tab 3)).) Petitioner called her primary care physician on February 10, 2015, the same day she received her vaccination, to report pain in her ear[14] and tonsils[15] that began *the day before*. (Ex. P30, p.11.) The records reflect that this pain was not associated with popping, leaking, fever, or dizziness, and continued to worsen before ultimately resulting in facial paralysis on February 15, 2015. (Ex. A, pp. 2-3 (citing Ex. P30, pp. 12, 14, 17, 23), 5.) Thus, Dr. Cipriani persuasively opines that petitioner's condition began when her pain started, the day before she received her second Hep B vaccination. (*Id.* at 5.) While petitioner's expert is silent as to the ear pain preceding onset of petitioner's facial paralysis, at least some of her treating physicians similarly

[14] The February 10, 2015 record that first reports petitioner's ear pain indicates that her right ear was affected. (Ex. P30, p. 11.) However, a series of follow up phone records indicate that it was petitioner's left ear that was affected. (*Id*. at 12-23.) Reading the records as a whole, it is clear that the February 10, 2015 call references the same ear pain as the subsequent calls. There is no other indication that petitioner ever had right ear pain and no reference to petitioner ever having had bilateral ear pain even when other symptoms are specified as bilateral. (*E.g.*, Ex. P12, p. 1.) Petitioner's affidavit mentions only left ear pain. (Ex. P1, p. 2.)

[15] Dr. Cipriani explains that the 7th cranial nerve that is affected by facial nerve palsies, such as Bell's palsy, provides sensation to the palate. Accordingly, petitioner's characterization of the pain encompassing the area of the tonsils in addition to the ear is consistent with Bell's palsy. (Ex. A, p. 5.)

accepted that the left ear and neck pain constituted the onset of her condition. (*E.g.*, Ex. P3, p. 1.) As explained above, this timing of onset is not compatible with any inference of vaccine-causation relative to either of her two Hep B vaccinations.

Beginning with her telephone call of February 13, 2015, petitioner's later medical records begin to include histories reflecting a later onset in the day or so *following* the second vaccination (Ex. P30, p. 14), instead of the day before as she had initially reported (*Id*. at 11). However, it is important to note that these histories continue to reflect an understanding by petitioner that her initial pain was a part of her relevant clinical presentation. It is simply the case that as time went on, petitioner began to incorrectly state that onset of that pain occurred after vaccination, whereas the actual contemporaneous medical record shows it began prior to vaccination. (*Id.*) Thus, for example, petitioner's affidavit presents earache as her first relevant symptom while incorrectly placing onset of that condition "[w]ithin approximately one day" of her vaccination. (*Compare* Ex. P1, ¶ 8, *with* Ex. P30, p. 11; *see also supra* note 14.) The later histories and affidavit account provided by petitioner are due less weight than the contemporaneous medical record. *See e.g.*, *R.K. ex rel. A.K. v. Sec'y of Health & Human Servs.*, No. 03-0632V, 2015 WL 10936124, at *76 (Fed. Cl. Spec. Mstr. Sept. 28, 2015) (holding that more remote histories of illness do not have sufficient indicia of reliability to be credited over conflicting contemporaneous medical records and earlier reported histories), *motion for review denied*, 125 Fed. Cl. 57, *aff'd per curiam*, 671 Fed. App'x 792 (Fed. Cir. 2016); *see also, e.g.*, *Vergara v. Sec'y of Health & Human Servs.*, 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those *recorded in later medical histories*, affidavits, or trial testimony." (emphasis added)). Although petitioner as a lay witness is not herself competent to address the clinical significance of her reported symptoms, the timing of her symptoms as reported in the contemporaneous record was within her personal knowledge. *James-Cornelius ex rel. E.J. v. Sec'y of Health & Human Servs*., 984 F3d 1374, 1380 (Fed. Cir. 2021) (noting that "for many medical symptoms," such as pain, "[m]edical records related to those symptoms would likely be based on the statements of those who experienced them").

Accordingly, for all the reasons discussed above, I find that petitioner has failed to meet her burden under *Althen* prong three.

c. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. Medical records are generally viewed as particularly trustworthy evidence. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master. *See* § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on

the special master or court"); *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). A petitioner may support a cause-in-fact claim through either medical records or expert medical opinion. *See* § 300aa-13(a). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.,* 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines,* 940 F.2d at 1528). Petitioner need not prove her vaccination was the sole cause of her injury, but must show that it was a substantial contributing factor and a "but for" cause. *Shyface*, 165 F.3d at 1352. Although petitioners do not bear a burden of eliminating other causes of injury, "evidence of other possible sources of injury can be relevant" to determining whether a prima facie showing has been made as to vaccine-causation. *Winkler,* 88 F.4th at 963 (emphasis omitted) (quoting *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012)).

In this case, petitioner's failure to meet her burden under *Althen* prongs one and three effectively precludes her from being able to satisfy *Althen* prong two. In the interest of completeness, however, I note that in addition to all of the above, Dr. Cipriani is also persuasive in opining that petitioner's condition is best understood as Ramsay Hunt syndrome, rather than idiopathic Bell's palsy, and that this therefore points to the varicella-zoster virus, rather than vaccination, as the cause of her condition.

Dr. Cipriani explains that patients diagnosed with Ramsay Hunt syndrome can suffer from additional symptoms, such as "erythematous vesicular rash in the ipsilateral ear, the hard palate, or on the anterior two thirds of the tongue." (Ex. A, pp. 4-5 (citing Sweeney & Gilden, *supra*, at Ex. A, Tab 4).) Consistent with Ramsay Hunt syndrome, this petitioner had a pimple-like rash on her tongue, face, and redness of the throat at the time of her diagnosis. (*Id.* at 8; *see, e.g.*, Ex. P42, p. 15.) Additionally, whereas there is no evidence to support Dr. Patel's assumption of a latent Herpes Simplex I virus, petitioner's medical history confirms she previously had chicken pox, which indicates the presence of latent varicella-zoster virus. (Ex. A, p. 4-5; Ex. 12, p. 1.) While most of petitioner's treating physicians diagnosed Bell's palsy, one of petitioner's treating physicians, otolaryngologist Dr. Bigelow, did specifically suspect Ramsay Hunt syndrome. (Ex. P5, p. 4.) Dr. Cipriani explains that a "[w]orkup to rule out alternative diagnoses should be done at the time of the facial nerve palsy" to determine whether the palsy is the result of reactivation of the varicella-zoster virus – meaning the correct diagnosis is Ramsay Hunt syndrome – or the etiology remains unknown – meaning the correct diagnosis is Bell's palsy. (Ex. A, p. 4.) This was not done in petitioner's case, effectively rendering any Bell's palsy diagnosis unreliable.

Furthermore, Dr. Cipriani asserts that post-vaccination inflammation is not consistent with the understood mechanism by which varicella-zoster virus is understood to be reactivated. Dr. Cipriani explains:

> There is no clear mechanism of why a vaccine would cause a patient to be at higher risk of a VZV (varicella zosters or shingles) infection. The biggest risk factors for developing shingles infection are advanced age and immunosuppression. If anything, a vaccine should activate the immune system, not cause immunosuppression.

(Ex. A, pp. 8-9.) Notably, in a prior case, *H.C. v. Secretary of Health & Human Services*, the petitioner presented a theory that a flu vaccination could cause reactivation of the varicella-zoster virus, which could then cause Ramsay Hunt syndrome. No. 16-4V, 2022 WL 2825395, at *27 (Fed. Cl. Spec. Mstr. May 9, 2022). The Special Master in that case reached the same conclusion, explaining that "the mechanism of [varicella-zoster virus] reactivation is not known. It has not been linked to vaccinations." *Id.*

Finally, petitioner's medical records do not reflect any treating physician opinion that would preponderantly support vaccine-causation. To be sure, there are some indications of petitioner's treating physicians at least entertaining the idea that her condition was secondary to her Hep B vaccine; however, that consideration was premised on petitioner's reports of onset occurring shortly *after* her February vaccination. (*Eg.*, Ex. P24, pp. 8, 11; Ex. P8, p. 7; Ex. P31, p. 6.) As explained above, under *Althen* prong three, that assumption is not preponderantly supported. Any medical conclusion is only as reliable as the underlying information. *See, e.g.*, *Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184, at *11 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) (explaining that "the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals."), *motion for review denied*, 133 Fed. Cl. 140 (2017).

Petitioner also submitted a letter by Dr. Robertson, in which he indicates,

> It is not possible to determine with 100% accuracy the exact virus or conditions that caused her [Bell's palsy], but had I known that there was a hepatitis B vaccination given within such a close proximity to the presentation of symptoms and office encounter, the possibility of a shot reaction would have been part of my differential diagnosis at that time.

(ECF No. 44-3.) Respondent contends that Dr. Robertson's opinion is "woefully deficient to satisfy *Althen* prong two." (ECF No. 70, p. 14.) I agree. Even setting aside the date of onset, Dr. Robertson conspicuously stops short of opining that petitioner's condition was caused by her vaccination.

In light of all of the above, there is no logical sequence of cause and effect between either of petitioner's Hep B vaccinations and her injury. Petitioner therefore has not met her burden of proof under *Althen* prong two.

d. Weighing the expert opinions

Finally, it bears stressing that, with regard to all of the points of analysis above, the mismatch in expert qualifications in this case heavily favors respondent's position. Respondent relies on a board-certified neurologist with direct clinical and academic experience with Bell's palsy. (Ex. A, p. 1.) She opines both, as a matter of general causation that there is not reliable scientific evidence supporting a causal relationship between the Hep B vaccine and Bell's palsy and, as a matter of specific caution that the evidence in this particular case instead favors Ramsay Hunt syndrome due to the varicella-zoster virus as the cause of petitioner's own symptoms. (*Id*. at 7-9.) Dr. Patel, by contrast, is a pharmacist and not a medical doctor. Although he indicates he is "an actively practicing clinical pharmacist," he explains that his areas of experience are in toxicology and adverse event investigation. (Ex. P40, p. 1.) He further explains that his experience with adverse event investigation has primarily involved taking record of potential side effects. (*Id*.) While Dr. Patel's curriculum vitae shows he has published on topics at the intersection of pharmacology and clinical medicine (most notably regarding sepsis and intensive care), nothing in his prior experience demonstrates any special facility with either Bell's palsy and its causes or the immune processes he proposes in this case as potentially leading to neurologic disease. (ECF No. 48-1.)

Where both parties offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). In determining whether a particular expert's testimony was reliable or credible, a special master may consider whether the expert is offering an opinion that exceeds the expert's training or competence. *E.g.*, *Walton v. Sec'y of Health & Human Servs.*, No. 04-503V, 2007 WL 1467307, at *17-18 (Fed. Cl. Spec. Mstr. Apr. 30, 2007) (otolaryngologist not well suited to testify about disciplines other than her own specialty). While experts with degrees in pharmacology have been permitted to testify in the past, the opinions of these experts are often outweighed by experts with degrees in medicine or qualifications uniquely situated to opine on the particulars of the case. *See, e.g.*, *McGuire v. Sec'y of Health & Human Servs.*, No. 10-609V, 2015 WL 6150598, *7-8 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) (finding that, although a pharmacist's citations included some useful information, her testimony "fell significantly short" and that a clinical pharmacist lacks the knowledge necessary to provide useful testimony regarding the causes of disease); *Rogero v. Sec'y of Health & Human Servs.,* No. 11-770V, 2017 WL 4277580, at *47 (Fed. Cl. Spec. Mstr. Sept. 1, 2017) (finding a pharmacist's qualifications "far inferior" to medical doctors regarding clinical and diagnostic opinions), *aff'd*, 748 Fed. App'x 996 (Fed. Cir. 2018). Where the experts in this case disagree with respect to matters of clinical medicine broadly and neurology specifically, I have placed greater weight on Dr. Cipriani's opinions.

VI. Conclusion

Petitioner has clearly suffered and she has my sympathy. However, for all the reasons discussed herein, petitioner has not preponderantly demonstrated that she actually suffered a *vaccine-caused* injury and is therefore not entitled to compensation. Accordingly, this case is dismissed.[16]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[16] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.